helpful suggestion.

In response to the Examiner's comment that "nitinol" is a registered trademark and should be identified as such, Applicant reiterates that the undersigned attorney performed an international trademark search on Dialog®, and an updated Dialog® search on February 16, 1998, and was able to find only one registration for the mark NITINOL, specifically NITINOL® (and design), as shown below.

DIALOG(R)File 226:TRADEMARKSCAN(R)-US Fed
(c) 1998 Thomson & Thomson. All rts. reserv.

03444097 * TRADEMARK IMAGE AVAILABLE *
NITINOL and Design
INTL CLASS: 10 (Medical Apparatus)
U.S. CLASS: 44 (Dental, Medical & Surgical Appliances)
STATUS: Registered; Section 8 - Accepted; Supplemental Register
GOODS/SERVICES: ORTHODONTIC WIRE
SERIAL NO.: 73-444,097
REG. NO.: 1,326,442
REGISTERED: March 19, 1985
FIRST USE: June 29, 1977 (Intl Class 10)
FIRST COMMERCE: June 29, 1977 (Intl Class 10)
FILED: September 16, 1983
AFFIDAVIT SEC.: 8; December 24, 1990
ORIGINAL APPLICANT: UNITEK CORPORATION (California Corporation), 2724 S. PECK RD., MONROVIA, CA (California), 91016, USA (United States of America)
ORIGINAL REGISTRANT: UNITEK CORPORATION (California Corporation), 2724 S. PECK RD., MONROVIA, CA (California), 91016, USA (United States of America)
ASSIGNEE(S): MINNESOTA MINING AND MANUFACTURING COMPANY (Delaware Corporation), 3M CENTER, SAINT PAUL, MN (Minnesota), USA (United States of America)
Assignor(s): UNITEK CORPORATION (California Corporation), 2724 SOUTH PECK ROAD, MONROVIA, CA (California), USA (United States of America)
Reel/Frame: 0735/0222
Recorded: August 27, 1990
Brief: ASSIGNS THE ENTIRE INTEREST AND GOOD WILL
DISCLAIMS: NO CLAIM IS MADE TO THE EXCLUSIVE RIGHT TO USE "NITINOL", APART FROM THE MARK AS SHOWN.
DESIGN PHRASE: THE MARK CONSISTS OF AN OUTLINE OF A U SHAPED ARCH CONNECTED IN A CONTINUOUS LINE WITH THE WORD "NITINOL".
FILING CORRESPONDENT: OFFICE OF PATENT COUNSEL, MINNESOTA MINING AND MANUFACTURING CO., 3M CENTER, P. O. BOX 33427, ST. PAUL, MN 55133-3427

This record indicates registration of a design mark for the word NITINOL used with orthodontic wire, but <u>not</u> for a metal alloy. No registration was located for the mark used in conjunction with the alloy, which the word is clearly meant to designate in the instant patent

application. It is improper to refer to a word as a trademark when it is not a trademark.

Further, Applicant directs the Examiner's attention to U.S. Patent No. 5,147,370 referenced in the International Search Report in parent International Application PCT/US95/06228, which includes multiple uses of the word "nitinol", even in the invention title, none of which indicate "nitinol" to be a trademark, either by the ™ symbol or the ® symbol.

In addition, Applicant notes that the Examiner also does not refer to the word "nitinol" as a trademark (see page 5, lines 11, 13 and 15 of the instant Detailed Action).

For the reasons stated above, Applicant declines to designate the word "nitinol" as a trademark.

The Examiner refers to the word "permanent" at line 2 of claim 11 as being unclear. Applicant refers the Examiner to claim 1, from which claim 11 depends, which states at lines 11-12 thereof "for providing permanent tissue support". Applicant has amended claim 11 in a clarifying manner to add this language.

Amendments to claim 15 adding the word "further" to line 1, and to claim 16 correcting an obvious typographical error have been made in accordance with the Examiner's helpful suggestions. Applicant declines to amend claims 12-19. Claim 11, from which claims 12-19 depend, recites that the device is a stent, which provides proper support for reciting "The stent of claim 11" in claims 12-19.

As all §112 issues are obviated by the foregoing amendments, withdrawal of the §112 rejection of claims 1-19 is respectfully requested.

Allowable Subject Matter

Claims 11-19 are stated to be allowable if rewritten in independent form in a manner which overcomes the stated §112 issues herein. In view of the foregoing amendments and the arguments which follow, claims 11-19 are believed to be allowable in their present form depending from claim 1. Applicant has added new claim 20 which is also believed to be in condition for allowance.

Claims Rejections - 35 U.S.C. §102(e) or §103

Claim 1-5 and 8 are rejected under §102(e) as being anticipated by or alternatively under §103 as being obvious in view of Cardon et al. 5,383,892. The Examiner states:

> With regard to claims 1-5 and 8, Cardon et al. anticipates the claim language when the "member" is interpreted to include only the self expanding portion of Cardon et al., because Cardon et al. discloses that flexible stents are known and are self-expanding as those described in EP 0183372; see the whole document of Cardon et al., especially col. 1, lines 24-30 and the Figures. EP 0183372, which is apparently incorporated into Cardon et al., discloses self-expanding stents so one could consider the flexible stent portion of Cardon et al. to be self-expanding; see the whole document, especially the abstract; Figure 3 and the portion of the description pertaining to Figure 3. Furthermore, the self-expanding material of Cardon et al. would evidently be capable of expanding if unconstrained, that is, detached from the rigid end stent portions. Additionally, the intermediate step of partial self-expansion would inherently occur if the Cardon et al. Stent were tightly fit into a catheter prior to insertion, wherein the removal therefrom would permit the flexible portion to bulge somewhat.
>
> Alternatively, if one does not consider the claim anticipated because there is no explicit teaching of a partially expanding stent with Cardon et al., the Examiner posits that the present claims are at least obviated thereby because the mere intermediate step of partial expansion is obvious in view of Cardon et al. which needs to be deformably expanded most if not all the way. It would have been clearly obvious to make the graft of Cardon et al. partially self-expanding so that a balloon expansion device could be more easily fit with it.

Claims 1-5 and 8 are not anticipated by Cardon et al. The Examiner's rationale is not well taken. Cardon et al. neither discloses, teaches nor suggests a tissue supporting device comprising a constrainable, self-expanding member as set forth in claim 1, from which claims 2-5 and 8 depend. Cardon et al. neither disclose, teach nor suggest a self-expanding member which is constrainable to a deployable diameter, and self-expands when unconstrained to an initially deployed diameter, as set forth in claim 1. In addition, Cardon et al. neither disclose, teach nor suggest such a device further comprising a first portion of a resilient self-expandable material and a second portion of a deformable and substantially less resilient material than the first portion as set forth in claim 1.

Cardon et al. appears to disclose a stent which is only radially expanded by a balloon (col. 4, lines 44-50), the stent comprising two axially rigid cylindrical parts at its two ends, the axially rigid cylindrical parts being adapted to be radially expanded in a plastic manner when the stent is expanded by a balloon, and the at least one axially flexible cylindrical part being adapted to be radially expanded in a plastic manner when the stent is expanded by a balloon.

The stent disclosed by Cardon et al. is not a self expanding member, as set forth in instant claim 1. Further, no portion of the stent disclosed by Cardon et al. is self-expanding--there is no disclosure, teaching or suggestion of self-expansion provided by Cardon et al. Contrary to the Examiner's position, the claims are not "at least obviated" by Cardon et al.

It is not understood why EP 0 183 372 is discussed. Contrary to the Examiner's position, EP 0 183 372 is not incorporated into Cardon et al. by reference. Furthermore, a combination of Cardon et al. and EP 0 183 372 is not motivated by either reference. Like Cardon et al., EP 0 183 372 neither discloses, teaches nor suggests a tissue supporting device comprising a self-expanding member which further comprises a first portion of a resilient self-expandable material and a second portion of a deformable and substantially less resilient material than the first portion, as set forth in claim 1.

Applicants do not consider claims 1-5 and 8 to be anticipated by Cardon et al., or to be rendered obvious by Cardon et al., either singly or in combination with EP 0 183 372.

For the reasons stated above, withdrawal of the stated §102(e) or §103 rejection of claims 1-5 and 8 is respectfully requested.

Claims Rejections - 35 U.S.C. 103(a)

Claims 6, 7, 9 and 10 are rejected under §103(a) as being obvious in view of Cardon et al. as applied to claims 1-5 and 8, further in view of Hess (WO 92/19310). The Examiner states:

> Cardon et al. at least obviates the claim language as set forth in the earlier rejection, but lacks the various materials (such as the different phases of austenite and martensite or the nitinol) as claimed. However, Hess teaches that it has been known to use phase changing materials of nitinol in similar stents; see the whole document, especially page 3, line 25 to page 5, line 34 and page 10, lines 3-8. Hence, it is the Examiner's position that it would have been obvious to utilize stents made of nitinol with various phases in the Cardon et al. invention so that the stent could be modified, on site, to the particular situation at hand.

In view of the arguments stated above with regard to the §102(e)/103 rejection

of claims 1-5 and 8 in view of Cardon et al., which are incorporated herein by reference, Applicant posits that any rejection of claims 6, 7, 9 and 10 based on Cardon et al. is without merit.

Claims 6, 7, 9 and 10 are not rendered obvious by Cardon et al., either singly or in combination with Hess. Neither Cardon et al. nor Hess discloses, teach or suggest a permanent tissue supporting device comprising a constrainable, self-expanding member which is constrainable to a deployable diameter and self-expands when unconstrained to an initially deployed diameter, which device further comprises a first portion of a resilient self-expandable material and a second portion of a deformable and substantially less resilient material than the first portion as set forth in all of the claims. Neither reference discloses such a member which following self expansion may be deformed due to the deformability of the second portion by an external force to radially enlarge the member to an enlarged fully deployed diameter for providing permanent tissue support as set forth in all of the claims.

Cardon et al. appears to disclose a stent which is only radially expanded by a balloon (col. 4, lines 44-50), the stent comprising two axially rigid cylindrical parts at its two ends, the axially rigid cylindrical parts being adapted to be radially expanded in a plastic manner when the stent is expanded by a balloon, and the at least one axially flexible cylindrical part being adapted to be radially expanded in a plastic manner when the stent is expanded by a balloon.

Despite its mention at page 1, lines 20-22 of a device capable of releasing stored energy to expand upon actuation within the body, Hess provides no motivation to provide such

a feature. Hess appears to disclose a shape memory alloy stent which is inserted, mechanically deformed following insertion, and subsequently removed by heating the alloy to the austenitic state, whereupon the stent regains its smaller insertion configuration.

The present invention as set forth in claims 6, 7, 9 and 10 is directed to a permanent self-expanding stent. Hess neither discloses, teaches nor suggests a permanent stent. Hess appears to be directed to a recoverable, removable stent which is not self-expandable, wherein the stent is transformed by heat to its austenitic phase which has a smaller configuration for removal.

Furthermore, neither Cardon et al. nor Hess disclose such a self expanding device wherein the first and second portions are comprised of a shape memory alloy, austenite and martensite, respectively, as set forth in claim 6.

Further, the present invention as set forth in claim 7, is directed to a stent as set forth in claim 6 wherein the first and second portions are in the form of layers in overlying relationship. Hess appears to disclose a recoverable stent which is inserted and deformed while in its martensitic state and subsequently transformed into its austenitic state for removal. Hess does not disclose, teach or suggest a superelastic austenitic alloy portion.

Neither Cardon et al. nor Hess disclose, suggest or teach the arrangement set forth in claim 7. One skilled in the pertinent art would not find sufficient motivation in Hess to provide same.

Claim 9 is directed to the device according to claim 1 wherein the first component is comprised of a nitinol alloy. The arrangement set forth in claim 1 having a first

component comprised of a nitinol alloy is neither disclosed, suggested nor taught by the cited references.

Further, claim 10 is directed to a device as in claim 1 wherein the first component is superelastic and the second component is any deformable material. As defined in the instant specification at page 5, lines 3-14, such superelasticity is present in the austenitic state. Nowhere in Hess is the claimed arrangement set forth. Hess appears to disclose a stent which is inserted and deformed while in its martensitic state and subsequently transformed into its austenitic state for removal. Nowhere in Hess is the claimed arrangement set forth. No suggestion of such an arrangement is made in the Cardon et al. reference.

There is no motivation for the cited combination, unless it is based on impermissible hindsight in view of Applicant's disclosure.

For the reasons stated above, the rejection of claims 6, 7, 9 and 10 under §103 in view of Cardon et al. and Hess is without basis. Withdrawal is respectfully requested.

CONCLUSION

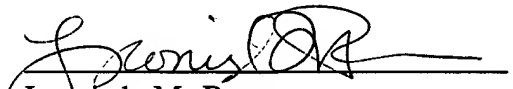
In view of the foregoing amendments and arguments, all of the claims, i.e. claims 1-19 and new claim 20 are believed to be in condition for allowance. Early notice to that effect is urgently solicited.

This response is being filed with a one month extension of time along with the fee of $110.00. In the event that this response requires an additional extension of time please charge any outstanding fee to our Deposit Account No. 22-0350.

Respectfully submitted,

Vidas, Arrett & Steinkraus, P.A.

Dated: February 17, 1998

By: 
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